K081672

AUG 15 2008

**SECTION 5 - 510(K) SUMMARY OF SAFETY & EFFECTIVENESS**

**DISCASSIST™ SYSTEM**

**510(k) Number K_____**

**Applicant's Name:**


| | |
|---|---|
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**Contact Person:**


| | |
|---|---|
| Official Correspondent: | Ahava Stein |
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**Name of the device:**

C-InSight System

**Trade or proprietary name, if applicable:**

C-InSight System

**Common or usual name:**

3-D Reconstruction Tool for Mobile X-ray Devices.

**Establishment Registration No.:**

3005075696

**Classification Name:**

System, Image Processing, Radiological

**Classification:**

FDA has classified Radiological Image Processing systems as a Class II medical device, with product code LLZ and 21 CFR classification code 892.2050. Review by the Radiology Panel.

**Predicate Device:**

The C-InSight™ system is substantially equivalent to the Siremobil Iso-C 3D software (manufactured by Siemens Medical Systems, Inc. and subject of 510(k) document no. K003266, K032280, K040347) and O-Arm Imaging System software (manufactured by Breakaway Imaging and subject of 510(k) document no. K050996 and K060344).
A comparison table and detailed discussion are presented in Section 12 of this application.

**Device Description:**

C-InSight is a software based product, which converts a sequence of Two-dimensional fluoroscopy images into a 3D volume, intraoperatively. The C-InSight is an add-on to commercially available mobile x-ray systems.
Two-dimensional imaging is available nowadays in every operating room in the form of a mobile C-Arm. However, there is often a need for a three-dimensional imaging

during the operation especially due to the rise in the scope of minimally invasive procedures.

To answer the need for a reasonably priced, easy to use and highly mobile intra-operative 3D imaging, the C-InSight was developed.

C-InSight is a software-based product, which gives the solution for 3D imaging intra-operatively, using a standard 2D Mobile C-Arm.

Coupling the 3D capabilities of the C-InSight using existing C-Arms in the operating rooms, can give surgeons a real-time assessment of implant placement.

The clinician who uses the C-InSight should identify the anatomical area which is scanned, and cover it with the C-InSight Reference Belt. The user scans the body and the C-InSight Reference Belt for 20 seconds. The scanned data is sent to the C-InSight processing unit, which converts this data into three-dimensional volume.

The clinician is then able to view the scanned data in different anatomical projections: AP, LT, AX and 3D volume.

The main components of the C-Insight system include:

A. Workstation
B. Accessories, including C-InSight Reference Belt and Image Adaptor
C. Disposable kit, including C-InSight Sterile Sheath

**Intended Use / Indication for Use:**

The C-InSight software provides a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image.

It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects particularly for orthopedic applications.

**Comparison of Technological Characteristics with the predicate device:**

The C-InSight system is similar to the predicate device regarding intended use and regarding technological characteristics. All are intended to be used when the clinician and patient benefit from generated 3D imaging of high contrast objects. They all include software which provides conversion of 2D fluoroscopic projections from C-Arms into a volumetric 3D image. The C-InSight system uses a reference belt and target recognition algorithms to calculate the relative projection and location coordinates of each image, while the predicate devices use built-in sensors to receive these coordinates.

**Non-Clinical Performance Data**

The following performance tests were conducted on the C-InSight system:

1. Software Validation (IEC 60601-1-4 & FDA Guidelines)
2. C-InSight synthetic accuracy test.
3. C-InSight spine accuracy test.
4. C-InSight accuracy vs. CT (cadaver tests)
5. Image Quality test
6. Radiation Dose Exposure test

## Clinical Performance Data

Not Applicable

**Conclusions Drawn from Non-Clinical and Clinical Tests:**

The performance tests demonstrate that C-InSight system may be safely and effectively used in surgical operation rooms, as an 3D visualization software, particularly for orthopedic applications. The software validation and accuracy performance tests demonstrate that the C-InSight system meets its design and performance specifications and is substantially equivalent to the previously cleared systems.

**Substantial Equivalence:**

In summary, the intended use of the C-Insight system is substantially equivalent to a combination of the Siremobil Iso-C 3D system and the O-Arm Imaging System. Furthermore, the basic technological characteristics of the C-InSight system are identical to the predicate devices. The differences in the technological characteristics do not raise new questions of safety and effectiveness. Consequently, the C-InSight system is substantially equivalent to the Siremobil Iso-C 3D system and the O-Arm Imaging System device.

**Performance Standards:**

The C-InSight$^{TM}$ system complies with the voluntary recognized standards:

1. Software Validation (IEC 60601-1-4 & FDA Guidelines)
2. Medical Electrical Equipment (IEC 60601-1 / 2)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2008

Mazor Surgical Technologies Ltd.
% Ms. Ahava Stein/ Ofer Hornick
Consultant
A. Stein – Regulatory Affairs Consulting
20 Hata'as St., Kfar Saba, 44425
ISRAEL

Re: K081672
Trade/Device Name: C-Insight System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 11, 2008
Received: June 13, 2008

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## INDICATIONS FOR USE

**510(k) Number (if known):**_____

**Device Name:** C-InSight System

**Intended Use Statement:**

The C-InSight software provides a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image.
It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects particularly for orthopedic applications

Prescription Use __√___ (Per 21 C.F.R. 801 Subpart D) OR Over-The-Counter Use___ (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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adiological Devices
510(k) Number K081672